

Section 5: 510(k) Summary

K108971

1.0 Submitted By:

SEP 27 2010

Gary Zhu, President

Hangzhou ATek Medical and Textile Co. Ltd.

Suite No. 503

Xi Xia Yuan No. 514

Hangzhou 310006

Zhe Chiang Province, China

Establishment Registration Number: 9615944

Primary Contact:

Glen Feye, President

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2.0 Date Submitted: September 22, 2010

3.0 Device Name(s):

3.1 Proprietary Names

Hangzhou ATek Medical &Textile Surgical Gowns, Various

MATERIAL	GOWN STYLE	STERILE/NON	Sizes	Model number
SMS	Reinforced	Non Sterile	L/XL/XXL	AKSG74100
	Reinforced	Sterile	L/XL/XXL	AKSG74700
	Reinforced with Guider	Non Sterile	L/XL/XXL	AKSG78100
	Reinforced with Guider	Sterile	L/XL/XXL	AKSG78700
HYDRO- ENTANGLED (Spunlance)	Non-reinforced	Non Sterile	L/XL/XXL	AKSG80100
	Non-reinforced	Sterile	L/XL/XXL	AKSG80700
	Non-reinforced with guider	Non Sterile	L/XL/XXL	AKSG82100
	Non-reinforced with guider	Sterile	L/XL/XXL	AKSG82700
	Reinforced	Non Sterile	L/XL/XXL	AKSG84100
	Reinforced	Sterile	L/XL/XXL	AKSG84700
	Reinforced with Guider	Non Sterile	L/XL/XXL	AKSG88100
	Reinforced with Guider	Sterile	L/XL/XXL	AKSG88700
SFT	Reinforced	Non Sterile	L/XL/XXL	AKSG94100
	Reinforced	Sterile	L/XL/XXL	AKSG94700
	Reinforced with Guider	Non Sterile	L/XL/XXL	AKSG98100
	Reinforced with Guider	Sterile	L/XL/XXL	AKSG98700

3.2 Common Name

Surgical Gown

Product code - FYA (Gown, Surgical)

3.3 Classification Name

Gown, Surgical (21CFR 878.4040 Product code - FYA)

4.0 **Predicate Devices:**

Candidate	Predicate	Manufacturer	Docket Number
Hangzhou ATek Medical and Textile Surgical Gowns	IMC Surgical Gowns	International Medsurg Connections, Inc.	K052550
	Master & Frank Surgical Gowns (Sterile)	Master and Frank Enterprises, Co. LTD	K012186

5.0 **Intended Use:**

Disposable gowns are worn by operating room personnel during surgical procedures to protect both the surgical patient and OR personnel from the transfer of body fluids and particulate material.

Gowns provided as sterile and non-sterile.

Non-sterile surgical gowns are to be sold to OEMs, which require EtO sterilization according to the ISO 11135 standard. Sterile surgical gowns are to be sold directly to users and must be sterilized by an EtO cycle validated to ISO 11135 standard.

The following disposable surgical gown types and model numbers are included in this submission

MATERIAL	GOWN STYLE	STERILE/NON	Sizes	Model number
SMS	Reinforced	Non Sterile	L/XL/XXL	AKSG74100
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	Reinforced with Guider	Sterile	L/XL/XXL	AKSG98700

6.0 Comparison to Predicate(s):

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

Aspect/ Characteristic	Predicate Gowns	IMC Gowns K052550	Master Frank Gowns K012186
Indications For Use	Disposable gowns are worn by operating room personnel during surgical procedures to protect both the surgical patient and OR personnel from the transfer of body fluids and particulate material. Gowns provided as sterile and non-sterile.	Surgical Gown is intended to be used as patient protective coverings used to isolate incision sites and protect against contamination during surgical procedures. Gowns provided as sterile and non-sterile	Single Use article of surgical apparel worn by operator room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, particulate material. Sterile Surgical Gowns only
Class	2	2	2
Product Code	FYA	FYA	FYA
Device Description	Disposable Gowns manufactured from non-woven fabric. Various sizes and materials.	Disposable Gowns manufactured from non-woven fabric. Various sizes and materials.	Disposable Gowns manufactured from non-woven fabric. Various sizes and materials.
Model Numbers	Various	Various	Various
Material Characteristics	SMS/Hydro-Entangled (Spunlace), SFT	Multiple SMS and SPP (Spunlace)	SFT
Performance Testing	Flammability- CPSC 16 CFR 1610 Lint ISO 9073-10:2003 Tensile Strength- ASTM D5034	Flammability- CPSC 16 CFR 1610 Lint ISO 9073-10:2003 Tensile Strength- ASTM D5034	Flammability- 16 CFR Part 10 Lint IST 160.1 Tensile Strength- ASTM D5034
Performance Standards Used	AATCC 127 AATCC 42	AATCC 127 AATCC 42	AATCC 127 AATCC 42
Biocompatibility Standards Used	ISO 10933-5 ISO 10933-10	ISO 10933-5 ISO 10933-10	ISO 10933-5 ISO 10933-10 ISO 10933-11

7.0 Summary of Performance Data:

The information in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to devices already in commercial distribution. Equivalence is demonstrated through intended use, materials, design and testing methods.

Test Data Provided in this Submission

Standard or Guidance Document	Data Generated	Relevant Section of Submission
AAMI/ANSI/ISO 11135-1 2007, Medical Devices -Validation and Routine Control of Ethylene Oxide Sterilization	EtO Sterilization Validation Parameters	14
AAMI / ANSI / ISO 10993-7:1995, Biological evaluation of medical devices -- Part 7: EO Residual Determination	EO Residuals	14
AAMI / ANSI / ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing	Biocompatibility Testing Evaluation	15
AAMI / ANSI / ISO 10993-5: (1999 and 2009) Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	Cytotoxicity	15
AAMI / ANSI / ISO 10993-10:2002/Amd. 1:2006, Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization	Skin Irritation, intra-cutaneous reactivity & sensitization	15
AATCC Test Method 127-2008 Water Resistance: Hydrostatic Pressure Test	Hydrostatic Pressure - Water Resistance	18
AATCC Test Method 42-2007 Water Resistance: Spray Impact Penetration Test	Impact Penetration – Water Resistance	18
ASTM - D5034-2008 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Tensile Strength	18

Standard or Guidance Document	Data Generated	Relevant Section of Submission
ASTM – D5734-1995(2001) Standard Test Method for Tearing Strength of Nonwoven Fabrics by Falling-Pendulum (Elmendorf) Apparatus	Elmendorf Tear	18
ISO 9073-10:2003 - Textiles -- Test methods for nonwovens -- Part 10: Lint and other particles generation in the dry state	Gelbo Flex - Lint	18
CPSC 16 CFR 1610-2004 Standard for Flammability of Clothing Textiles	Flammability	18



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

Hangzhou Atek Medical & Textile Company, Limited
C/O Mr. Glen Feye
Accurate Consultants Incorporated
1340 West Pennsylvania Avenue
San Diego, California 92103

SEP 27 2010

Re: K100971

Trade/Device Name: Hangzhou ATEK Medical & Textile Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: September 10, 2010
Received: September 13, 2010

Dear Mr. Feye:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statements

K100971

Indications for Use

SEP 27 2010

510(k) Number (if known): **K100971**

Device Name: **Hangzhou ATek Medical &Textile Surgical Gowns**

Indications for Use:

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Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Clamie-Williams

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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